

510(k) Summary

JUL 11 2008

Trade Name: HydroSoft® and HydroSoft *Plus* Embolization Coil Systems with HES-HC-HS (10) Coils

Generic Name: Artificial Embolization Device

Classification: Class II, 882.5950
Class II, 870.3300

Submitted By: MicroVention, Inc.
75 Columbia, Suite A
Aliso Viejo, CA 92656

Contact: Kevin E. Daly

Predicate Devices: HydroCoil® Embolic System with (HES) with the HES-HC-HS (10) Coils (K070656)

Device Description:

The HydroSoft® and HydroSoft *Plus* Embolization Coil Systems with HES-HC-HS (10) Coils are platinum embolization coils with an inner hydrogel core, and a V-Trak™ Delivery Pusher.

Indications for Use:

The HydroSoft and HydroSoft *Plus* Embolization Coil Systems with HES-HC-HS (10) Coils are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula.

The HydroSoft and HydroSoft *Plus* Embolization Coils Systems also are intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

Comparison to Predicate Device:

The HydroSoft and HydroSoft *Plus* Embolization Coils Systems are similar in materials of construction and intended use to the predicate HydroCoil device, but are available in larger secondary diameters and longer lengths to suite the needs of the physician.

Summary:

Based upon the technical and performance attributes of the HydroSoft and HydroSoft *Plus* Embolization Coils Systems, these devices are substantially equivalent to the cited predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MicroVention, Inc.
% Mr. Kevin E. Daly
Vice President, Regulatory Affairs
and Quality Assurance
75 Columbia, Suite A
Aliso Viejo, California 92656

JUL 11 2008

Re: K080666

Trade/Device Name: HydroSoft® *Plus* Embolization Coil Systems with
HES-HE-HS (10) Coil

Regulation Number: 21 CFR 882.5950

Regulation Name: Neurovascular embolization device

Regulatory Class: II

Product Code: HCG

Dated: June 6, 2008

Received: June 9, 2008

Dear Mr. Daly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

12080666

Indications for Use

510(k) Number (if known): _____

Device Name: HydroSoft® and HydroSoft Plus Embolization Coil Systems with HES-HC-HS (10) Coils

Indications for Use:

The HydroSoft and HydroSoft Plus Embolization Coil Systems with HES-HC-HS (10) Coils are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula.

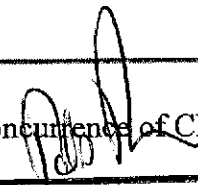
The HydroSoft and HydroSoft Plus Embolization Coils Systems also are intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)



Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 12080666

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